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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/526,582	03/16/2000	Judith Fitzpatrick	SRX 110	1732

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EXAMINER	
COUNTS, GARY W	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/526,582	Applicant(s) FITZPATRICK ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the claims

The amendment filed on February 25, 2003 is acknowledged and has been entered.

Claims 1-22 are pending and are under examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is vague and indefinite in reciting, "as separate reagents, antibodies to" because it is unclear how this instant reagent in claim 19 relates to the "reagents for detection in claim 17, which is further comprised in the kit or device.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3, 5-7, 10-14, 16-18 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt (US 5,677,133) or Oberhardt (US 5,601,991 in view of Fellman et al (US 5,112,758) and further in view of Schneider (US 6,291,178) for reasons set forth in the previous office action.

5. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kudu et al (US 6,210,906) in view of Fellman et al. (US 5,112,758) and in further view of Schneider (US 6,291,178) for reasons set forth in the previous office action.

6. Claims 8-9, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt (US 5,677,133) or Oberhardt (US 5,601,991) in view of Fellman et al. (US 5,112,758) and in further view of Schneider (US 6,291,178) as applied to claims 1-3, 5-7, 10-14, 16-18 and 20-22 above, and further in view of Fisher et al. (Diabetes Research and Clinical Practice, 1991) and Coppo et al. (Journal of Diabetic Complications, 1987) for reasons set forth in the previous office action.

Response to Arguments

Applicant's arguments filed February 25, 2003 in paper no. 20 have been fully considered but they are not found persuasive.

Applicant argues that Schneider (US 6,291,178) is not prior art because U.S. patent 6,291,178 to Schneider issued on an application filed August 30, 1999. The present application claims priority to US.S.N. 60/124,562 filed March 16, 1999. Applicant argues that although Schneider claims priority to U.S.S.N 08/978,729 filed November 26, 1997, a review of U.S. Patent 5,968,746 is drawn entirely to the use of a saliva sample for measurement of drugs. This is not found persuasive because Schneider (US 5,968,746) is not drawn entirely for the measurement of drugs, but also includes the measurement of proteins (col. 2, line 43 claim 6 and claim 13. Further, Examiner has relied on Schneider for the teaching that it is known in the art to correlate a saliva sample with a blood sample to determine an amount of analyte of interest.

Applicant argues that both Oberhardt patents do not teach the detection of levels of apolipoprotein in saliva or a correlation between apolipoprotein in saliva. This is not found persuasive because as set forth in the previous office action Oberhardt discloses applying oscillating or moving static magnetic field to the reaction mixture to activate the reaction cascade initiator, monitoring the response of the magnetic particles to provide a signal, then determining the concentration of the apolipoprotein (col. 14 – col. 15). Oberhardt specifically discloses that another object of the invention is to provide convenient, rapid diagnostic tests for difficult biological samples, other than blood, such as saliva (col 3, lines 24-32 and col 4. lines 11-19). Examiner has not relied upon the Oberhardt reference for the correlation in saliva but rather has relied upon Schneider (US 6,291,178) for this teaching.

Applicant argues that Fellman does not teach detecting apolipoproteins in saliva with antibodies, or that the levels can be correlated with levels in serum. Examiner has not relied upon Fellman for these teachings. Examiner has relied upon Fellman for teaching the collection of saliva.

Applicant argues that Kundu does not teach why or how the levels of apolipoproteins should be detected in saliva nor how to correlate the levels of the apolipoproteins in the saliva with the levels of the apolipoproteins in the serum. This is not found persuasive because Kundu discloses detecting apolipoprotein A in a saliva sample by immunoreacting labeled monoclonal antibodies with the Apo A in the sample, specifically against kringle 5 domain of apo A (col. 4, lines 39-52, and column 8, lines 8-15). With respect to how to correlate the levels of the apolipoproteins in the

saliva with the levels of the apoplipoproteins in serum this limitation is taught by Schneider et al.

Applicant argues that Fisher and Coppo do not suggest detecting apolipoprotien in saliva, nor that the levels could be correlated with the levels in the serum by measuring the values of the albumin. This is not found persuasive because Examiner has not relied upon Fisher and Coppo for these limitations. Examiner has relied upon Fisher and Coppo for normalizing the amount of apolipoprotein to the amount of albumin present in the saliva sample and antibodies immunoreactive to albumin in the device or kit for determining apolipoprotein concentration.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
May 29, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
05/30/03